226/242
Docket

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

Cheng et al.

Serial No.: 08/900,559

Filed: 07/25/97

For: METHOD OF USE OF ONE STEP IMMUNOCHROMATOGRAPHIC DEVICE FOR STREPTOCOCCUS A ANTIGEN

Group Art Unit: 1641

Examiner: Carol A. Spiegel

December 1, 1998

DECLARATION OF RICHARD H. SCHWARTZ, M.D.

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

1. I received an M.D. from Georgetown University in 1965, and am practicing medicine with the Vienna Pediatric Associates in Vienna, Virginia. In the past 12 years I have evaluated several rapid diagnostic clinical tests to detect group A Streptococci. A copy of my CV is attached to this declaration as Exhibit 1.

CERTIFICATE OF MAILING
(37 C.F.R. §1.10)

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as 'Express Mail Post Office To Addressee' in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

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2. I have conducted comparison tests of the OSOM™ Strep A Test and the Quidel QuickVue™ In-Line Strep A Test, and the results have been published in The Pediatric Infectious Disease Journal, Vol. 16, No. 11 at 1099-1100, November 1997. A copy of this article is attached to this declaration as Exhibit 2.

3. The results set forth in Exhibit 2 show that the OSOM™ Strep A test had a greater sensitivity than the QuickVue™ Strep A test. The OSOM™ Strep A test had an overall sensitivity of 95%, while the QuickVue™ Strep A test had an overall sensitivity of 87%. Exhibit 2 at 1100. Both tests had a sensitivity of 100% for the detection of 3+ and 4+ Streptococcus growth (as demonstrated by growth of colonies on agar plates); however, while the OSOM™ Strep A test was 83% sensitive for 1+ cultures, and 86% for 2+ cultures, the QuickVue™ test was only 33% sensitive for 1+ cultures, and 72% sensitive for 2+ cultures. Exhibit 2 at 1100.

4. The OSOM™ Strep A immunodiagnostic test strips are not contained in a bulky plastic or cardboard housing, and are therefore compact enough to be directly inserted into a sample chamber small enough to permit efficient sample extraction. Because the time from the start of the sample extraction to initiation of the lateral flow immunoassay (by insertion of the device into the sample chamber) can be controlled, there is greater control over mixing of the sample with the reagents, and the length and efficiency of extraction. This results in greater sensitivity of the assay, compared to assays in which sample mixing, and the length and efficiency of extraction cannot be controlled.

In contrast to the OSOM™ Strep A test strip, the QuickVue™ device contains a bulky housing for the immunodiagnostic test strip. This housing contains a sample extraction chamber in flow communication with the test strip. In this device, flow from the sample extraction chamber onto the test strip begins almost as soon as the extraction reagents are added to the sample in the sample chamber. In strep A tests using these devices, samples cannot be mixed as vigorously with reagents as in a separate sample chamber, and there is less time for extraction prior to initiation of the assay. This results in a lower sensitivity of the immunodiagnostic test.

6. Other immunoassays available prior to these one-step tests required further manipulation, e.g., transfer, of the sample following sample extraction. This introduced additional sources of error into the tests, requiring that the tests be performed by more qualified personnel.

I hereby certify that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patents issued thereon.

Dated: November 23, 1998

Richard Schwartz, M.D.
Richard H. Schwartz, M.D.